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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,062	07/19/2001	Anil K. Saksena	JN01157K	9813

24265 7590 03/26/2003  
SCHERING-PLough CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER
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AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/909,062	SAKSENA ET AL.
	Examiner Maury Audet	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

#### THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 July 2002.  
     2b) This action is non-final.  
 2a) This action is FINAL.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.  
     4a) Of the above claim(s) 34,36-39,41-44 and 47-52 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-33,35,40,45,46,53 and 54 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) All b) Some \* c) None of:  
         1. Certified copies of the priority documents have been received.  
         2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 5.

- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other:

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## **DETAILED ACTION**

### **Change of Art Unit Designation**

1. Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1648 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

### **Preliminary Amendment**

2. Applicant's Preliminary Amendment, filed February 13, 2003, Paper No. 10, is acknowledged.

### **Election/Restrictions**

3. Applicant's election, with traverse, of Group I, claims 1-33, 35, 40, 45, 46, 53, and 53 and 54, as drawn to the elected compound invention of claim 40 (bottom of specification page 174), in Paper No. 7 is acknowledged. The traversal is on the ground(s) that "claims 1-54 form part of one and the same invention, with the commonality of two generic structures (Formula I and Formula II)" and that due to this commonality a search of all structures would not be an undue burden. Applicant further argues that "the same art search will most probably apply to all of the alleged separate inventions." This is not found persuasive. First, Groups II and III fall within different classes than Group I, requiring different searches, thus restriction of the various groups was proper. Second, the former Examiner required in Paper No. 6, and this Examiner agrees, based on the different structures of the compounds in Group I, a different search for each individual compound would have been required by the Office to examine the prior art of the respective compounds/inventions. The areas of commonality would not have negated this requirement. Their different chemical, physical, and/or pharmacological properties, necessitate

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separate structural and sequence searches and separate analysis for enablement and patentability. Each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary. Applicant has not provided any evidence that each compound is *not* a patentably distinct invention a single. Thus, under MPEP §803(B), restriction is proper when there is a serious burden, thus warranting restriction of Groups I-III, and the compounds of Group I.

However, applicant may file an express admission that the claimed inventions (subgroups) are obvious over each other within the meaning of 35 U.S.C. 103, wherein the restriction requirement as to the subgroups will be removed. *See In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

The requirement is still deemed proper and is therefore made FINAL.  
As part of the response to this action, Applicant is asked to specifically cancel the non-elected claims.

**Domestic Priority under 35 U.S.C. § 119 (e)**

4. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

**Information Disclosure Statement**

5. The Supplemental Information Disclosure Statement (IDS) filed July 18, 2002, Paper No. 5, has been considered. An initialed copy of Form PTO-1449 in accordance with MPEP § 609 is attached. The file jacket listed that an IDS was also filed January 3, 2002, Paper No. 4. There

was not a Form PTO-1449 found in the file, as to this filing. Applicant is asked to submit a supplemental copy of this, and references if different than those in Paper No. 5, if necessary.

#### **Status of the Claims**

6. Claims 1-54 were originally filed in the present application. The claims were subject to restriction, Paper No. 6. Applicant elected, with traverse, Group I, claims 1-33, 35, 40, 45, 46, 53, and 53 and 54, as drawn to the elected compound invention, compound #21 of claim 40 (bottom of specification page 174). Claims 34, 36-39, 41-44, and 47-52 are withdrawn from consideration. Claims 1-33, 35, 40, 45, 46, 53, and 53 and 54, as drawn to the elected compound #21 of claim 40, are pending and examined on the merits.

#### **Disposition of Elected Compound**

7. The claimed invention, as elected in claims 1-33, 35, 40, 45, 46, 53, and 53 and 54, is drawn to the elected invention peptide compound #21/54 of claim 40 (bottom of specification page 174), and enantiomers, stereoisomers, rotomers, and tautomers of elected compound #21 of claim 40. This specific elected compound, peptide #21 of claim 40, has been determined to be free of the prior art, and is patentable.

#### **Rejections**

#### **35 U.S.C. § 112, 1st ¶, Written Description**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33, 35, 40, 45, 46, 53, and 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

*Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

As discussed supra, the claimed invention, as elected in claims 1-33, 35, 40, 45, 46, 53, and 53 and 54, is drawn to the elected invention peptide compound #21/54 of claim 40 (bottom of specification page 174), *and enantiomers, stereoisomers, rotomers, and tautomers of elected compound #21 of claim 40*. The specification has not defined the structures associated with the broad genus of "enantiomers, stereoisomers, rotomers, and tautomers of elected compound #21 of claim 40." Only the structure of elected compound #21 of claim 40, can be determined based on the specification.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* compound #21 of claim 40. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, claim 1 encompasses numerous species that are not further described, namely enantiomers, stereoisomers, rotomers, and tautomers of elected compound #21 of claim

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40. As the fragments will contain different structures from compound #21 of claim 40, there is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which includes the enantiomers, stereoisomers, rotomers, and tautomers of elected compound #21 of claim 40. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Amending the claims to be limited to the specifically elected compound #21 of claim 40, would likely receive favorable consideration. Such an amendment, in combination with a response fully addressing the written description issues would likely place the case in condition for allowance.

#### **Relevant Prior Art**

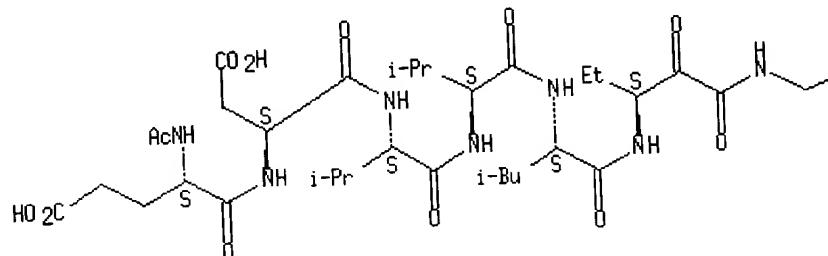
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Tung et al. (U.S. Patent No. 6265380 B, Issued July 24, 2001, Continuation of PCT/US97/18968, filed on October 17, 1997, and published as WO 98/17679 on April 30, 1998; latter cited in Applicant's IDS, Paper No. 5). During the search of elected compound #21 of claim 40, prior art was discovered that teaches core Formula I of claim 1, and any of the elected claims, and their respectively distinct chemical structures, that read upon core Formula I.

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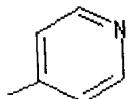
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Tung et al. teach compound, L-Leucinamide, N-acetyl-L-a-glutamyl-L-a-aspartyl-L-valyl-L-valyl-N-[(1S)-1-ethyl-2,3-dioxo-3-[(4-pyridinylmethyl)amino]propyl]- (9CI); [RN 207001-88-5; in STN Files CA, CAPLUS, USPATFULL] (See References Cited):

PAGE 1-A



PAGE 1-B



A residue-by-residue analysis of the above structure teaches each of the limitations of core

Formula I, claim 1.

### Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

March 19, 2003

*Brenda Brumback*  
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